

मिसिलस.- 8(122)/2024/डी.पी/एनपीपीए-डीवी-II
F. No. 8(122)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 254/122/2024/F
Proceeding No: 254/122/2024/F

Minutes of the 254th (overall) and 122nd meeting of the Authority under DPCO, 2013 held on 20.03.2024 at 03:00 PM.

The 254th meeting of the Authority (overall), which is the 122nd meeting under the DPCO, 2013 was held on 20th March, 2024 at 03:00 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Shri Antony Cyriac, Economic Advisor, Department of Economic Affairs

Shri Ranga Chandrashekar, Deputy Drugs Controller, CDSCO, Ministry of Health & Family Welfare was also present.

The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

- (i) Shri Sanjay Kumar, Advisor (Cost)
- (ii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iii) Shri. Mahaveer Saini, Deputy Director (Pricing)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 121st Meeting held on 20.02.2024.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 121st Meeting held on 20.02.2024.

2.1 Noted.

3. Agenda item no. 3 – Status of New Drug applications

3.1 Noted.

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xlvii) (total 76 Form I applications containing retail price fixation of 76 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 65(Sixty five) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in Table 1, Table 2 & Table 3:

Table No. 1: Retail Price Fixation

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each film coated Bilayered Tablet Contain: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	14.00
4 (v)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each film coated Bilayered Tablet Contain: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	15.32
4 (vi)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each film coated Bilayered Tablet Contain: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	15.32
4 (vii)	Sitagliptin, Pioglitazone and Metformin Hydrochloride	Each film coated Bilayered Tablet Contain: Sitagliptin Phosphate	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s	14.00

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	(Sustained Released) Tablet	Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)		Mankind Pharma Ltd.	
4 (viii)	Metoprolol Succinate Extended Release, Amlodipine and Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release) Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Ajanta Pharma Limited / M/s Sun Pharma Laboratories Limited	14.60
4 (ix)	Linagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Linagliptin IP 5mg Metformin Hydrochloride IP 500mg (As Extended release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Lupin Limited	13.03
4 (x)	Vitamin D3 (Cholecalciferol) Oral Solution	Each 5 ml syrup contains: Cholecalciferol IP 60000IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	12.53
4 (xi)	Cholecalciferol (Vitamin D3) Oral Solution 60000IU	Each 5ml contains: Cholecalciferol IP (In nano Droplet form) 60000IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	13.60
4 (xii)	Linagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Morepen Laboratories Limited	8.97
4 (xiii)	Phenylephrine Hydrochloride, Chlorpheniramine maleate, Paracetamol, Sodium Citrate & Menthol Syrup	Each 5 ml contains: Phenylephrine Hydrochloride IP 5mg Chlorpheniramine maleate IP 0.5mg Paracetamol IP 125mg Sodium Citrate IP 60mg Menthol IP 1mg	1 ml	M/s Tirupati Medicare Limited / M/s Macleods Pharmaceuticals Limited	0.95
4 (xiv)	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydramine Hydrochloride	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Caffeine (Anhydrous) IP	1 Tablet	M/s Aagya Biotech Pvt. Ltd. / M/s Macleods Pharmaceuticals Limited	3.70

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablet	30mg Diphenhydramine Hydrochloride IP 25mg			
4 (xv)	Linagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Linagliptin 5mg Metformin Hydrochloride (as Extended release) IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Micro Labs Ltd.	11.60
4 (xvi)	Cefpodoxime Proxetil & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 200mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Brooks Laboratories Ltd. / M/s German Remedies Pharmaceuticals Private Limited	28.49
4 (xvii)	Cefpodoxime & Potassium Clavulanate Oral suspension	Each 5ml reconstituted suspension contains: Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 100mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 62.50mg	1 ml	M/s Brooks Laboratories Ltd. / M/s German Remedies Pharmaceuticals Private Limited	4.94
4 (xviii)	Cilnidipine and Telmisartan Tablets	Each film coated tablet contains: Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	10.26
4 (xix)	Mefenamic Acid & Paracetamol Tablets	Each uncoated tablet contains: Mefenamic Acid IP 500mg Paracetamol IP 325mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Micro Labs Limited	3.58
4 (xx)	Pantoprazole & Domperidone Tablet	Each enteric coated tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg Domperidone IP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zuventus Healthcare Limited	7.04
4 (xxi)	Cefpodoxime & Potassium Clavulanate Oral suspension	Each 5ml of reconstituted suspension contains: Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 50mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg	1 ml	M/s Brooks Laboratories Ltd. / M/s German Remedies Pharmaceuticals Private Limited	3.17
4 (xxii)	Amoxycillin and Potassium	Each film coated tablet contains:	1 Tablet	M/s Malik Lifesciences Pvt.	17.46

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Clavulanate Tablets IP	Amoxycillin Trihydrate IP eq. to Amoxycillin 250mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg		Ltd. / Themis Medicare Ltd.	
4 (xxiii)	Amoxycillin and Potassium Clavulanate Oral suspension	Each 5ml of Reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg	1 ml	M/s Malik Lifesciences Pvt. Ltd. / Themis Medicare Ltd.	3.18
4 (xxiv)	Aceclofenac, Paracetamol & Thiocolchicoside Tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Thiocolchicoside IP 4mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	17.84
4 (xxv)	Linagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Morepen Laboratories Limited	7.92
4 (xxvi)	Linagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Morepen Laboratories Limited	9.60
4 (xxix)	Rosuvastatin + Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as light orange coloured film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two, light brown coloured film coated tablets, each containing Clopidogrel Tablet 37.5mg)	1 Capsule	M/s Windlas Biotech Ltd. / M/s Emcure Pharmaceuticals Limited	17.03
4 (xxx)	Rosuvastatin + Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as light orange coloured film coated tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two, light brown coloured film coated tablets, each containing Clopidogrel Tablets 37.5mg)	1 Capsule	M/s Windlas Biotech Ltd. / M/s Emcure Pharmaceuticals Limited	19.46

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xxxi)	Atorvastatin and Fenofibrate Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Fenofibrate IP 160mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	27.09
4 (xxxii)	Atorvastatin, Clopidogrel & Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As green coloured pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two reddish brown coloured film coated tablet, each containing 37.5mg Clopidogrel Tablets IP), Aspirin IP 75mg (As enteric coated white-coloured pellets)	1 Capsule	M/s Windlas Biotech Limited / M/s Eris Lifesciences Ltd.	13.84
4 (xxxiii)	Atorvastatin & Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As green coloured spherical pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two reddish brown coloured film coated tablet, each containing 37.5mg Clopidogrel Tablets IP),	1 Capsule	M/s Windlas Biotech Limited / M/s Eris Lifesciences Ltd.	26.88
4 (xxxiv)	Gliclazide & Metformin Hydrochloride Tablets	Each uncoated tablets contains: Gliclazide IP 40mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Mediforce Healthcare Pvt ltd / M/s Mankind Pharma Ltd	7.35
4 (xxxv)	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained release form) Metformin Hydrochloride IP 500mg (As Sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s USV Private Limited	9.67
4 (xxxvi)	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained release form) Metformin Hydrochloride IP 1000mg (As Sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s USV Private Limited	10.78
4	Dapagliflozin,	Each film coated	1 Tablet	M/s Mascot	13.24

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(xxxvii) a	Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg		Health Series Pvt. Ltd. / M/s Alkem Laboratories Limited	
4 (xxxvii) b	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	13.24
4 (xxxvii) c	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	14.92
4 (xxxvii) d	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s USV Private Limited	13.43
4 (xxxvii) e	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s USV Private Limited	15.11
4 (xxxvii) f	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Mankind Pharma Ltd.	15.11



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 2 mg			
4 (xxxvii) g	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Mankind Pharma Ltd.	13.43
4 (xxxvii) h	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Micro Labs Limited	12.50
4 (xxxvii) i	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Micro Labs Limited	13.39
4 (xxxvii) j	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Medley Pharmaceuticals Ltd.	13.43
4 (xxxvii) k	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Medley Pharmaceuticals Ltd.	15.11

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Glimepiride IP 2 mg			
4 (xxxvii) l	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Lupin Limited	13.43
4 (xxxvii) m	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Lupin Limited	15.11
4 (xxxviii) a	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Windlas Biotech Limited / M/s Emcure Pharmaceuticals Limited	14.44
4 (xxxviii) b	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Windlas Biotech Limited / M/s Emcure Pharmaceuticals Limited	16.12
4 (xxxviii) c	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Micro Labs Limited	14.29
4 (xxxviii) d	Dapagliflozin, Metformin Hydrochloride (Extended Release)	Each film coated bilayered tablet contains: Dapagliflozin Propanediol	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Micro Labs Limited	15.18

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	and Glimepiride Tablets	USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg			
4 (xxxviii) e	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / Dr. Reddy's Laboratories Limited	14.55
4 (xxxviii) f	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / Dr. Reddy's Laboratories Limited	16.23
4 (xxxviii) g	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	13.39
4 (xxxviii) h	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	14.29
4 (xxxviii) i	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	16.00



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xxxviii) j	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	14.55
4(xl)	Dapagliflozin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate IP eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	12.98
4(xli)	Dapagliflozin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate IP eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	11.30
4(xlii)	Dapagliflozin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate IP eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 500mg Glimepiride IP 1 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	9.91
4(xliii)	Dapagliflozin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate IP eq. to Dapagliflozin 5mg Metformin Hydrochloride IP 500mg Glimepiride IP 2 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	11.59
4(xliv)	Azelnidipine and Metoprolol Succinate (Sustained Release) Tablet	Each film coated bilayered tablet contains: Azelnidipine IP 16mg Metoprolol Succinate IP eq. to Metoprolol Tartrate 25mg (as Sustained release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	15.92
4(xlv)	Azelnidipine and Metoprolol Succinate (Sustained Release)	Each film coated bilayered tablet contains: Azelnidipine IP 16mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent	17.23

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablet	Metoprolol Succinate IP eq. to Metoprolol Tartrate 50mg (as Sustained release)		Pharmaceuticals Ltd.	
4(xlvi)	Mecobalamin, Zinc, Calcium Pantothenate, Vitamin B6, Folic Acid, Niacinamide & Chromium Tablets	Each film coated tablet contains: Mecobalamin IP 500mcg Zinc Sulphate Monohydrate IP 61.8mg (eq. to elemental Zinc 22.5mg) Calcium Pantothenate IP 10mg Pyridoxine Hydrochloride IP 3mg Folic Acid IP 1.5mg Niacinamide IP 50mg Chromium 50mcg (As Chromium Picolinate IP)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Blue Cross Laboratories Private Limited	4.97
(xlviii)	Ceftriaxone and Sulbactam injection	Each Combi pack Contains: Part-I Each vial contains: Ceftriaxone Sodium IP (Sterile) eq. to anhydrous Ceftriaxone 1000mg, Sulbactam Sodium IP (Sterile) eq. to Sulbactam 500mg Part-II (For Reconstitution) Each FFS Ampoule contains: Sterile Water for Injections IP 10ml	1 Vial	M/s East African (India) Overseas / M/s Softdeal Pharmaceuticals Private Limited	140.09 (Note 1)

Note 1- The Authority noted that the applicant vide email dated 20.02.2024 has requested for withdrawal of form I application citing non viability issue and commercial reasons. The Authority deliberated upon the matter and decided to reject the request of the applicant as the company has not represented against the draft working sheet uploaded by NPPA. Hence, retail price of Rs.140.09 per vial was approved.

4.2 The Authority noted that in the following three cases the companies have launched the product without obtaining prior price approval. Accordingly, the Authority deliberated upon the matter and approved the retail price as given in Table 2 below:

Table No. 2: Retail price fixation in without price approval cases

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(xlvii) c.	Remogliflozin	Composition:	1 Tablet	M/s Glenmark	8.76

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(A)	Etabonate, Vildagliptin & Metformin Hydrochloride tablets	Remogliflozin Etabonate 100mg Vildagliptin 50mg Metformin Hydrochloride IP 500mg tablets		Pharmaceuticals Limited	(Note: 2)
(xlvii) c.(B)	Remogliflozin Etabonate, Vildagliptin & Metformin Hydrochloride tablets	Composition: Remogliflozin Etabonate 100mg Vildagliptin 50 mg Metformin Hydrochloride IP 1000 mg tablets	1 Tablet	M/s Glenmark Pharmaceuticals Limited	9.06 (Note: 2)
(xlvii) d	Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Ceftazidime (As Ceftazidime pentahydrate) IP 2gram Avibactam Sodium eq. to Avibactam 0.5gm	1Vial	M/s BDR Pharmaceuticals International Pvt. Ltd. / M/s Natco Pharma Limited	1696.43 (Note: 3)

Note 2: The Authority noted that the company had suo moto invoked Para 32 and launched the product without prior price approval in October, 2021 for the formulation at Sr. No.(xlvii) c. (A) and in November 2021 for the formulation at Sr. No. (xlvii) c.(B). Since Para 32 is not self invocable, the Authority decided that price may be fixed. Accordingly, the Authority approved the price worked out on the basis of March, 2021 data for the formulation at Sr. No.(xlvii) c. (A) and on the basis of April, 2021 data for the formulation at Sr. No.(xlvii) c. (B) i.e. on the basis of month ending immediately before six months prior to the launch of the formulation. **The Authority approved the launched price, it being lower than the worked out price.**

Note 3: The Authority noted that the company has already launched the product in April 2023 at a price lower than the worked out price. Accordingly, the Authority approved the launched price as the same is the lowest of claimed price, worked out price and the launch price of the company.

4.3 With respect to the following applications for retail price approval, it was brought to the notice of the Authority that it is learnt that the Drug Control Authorities have suspended/ cancelled licence issued in the name of M/s Synokem Pharmaceuticals Limited. It was informed to the Authority that NPPA has sought confirmation about the same from the office of DCGI and State Licensing Authority (SLA) vide letter dated 11.03.2024 and followed by reminder e-mail dated 15.3.2024. The reply of the same is still awaited from DCGI as well as the SLA.

4.4 The matter was discussed in detail and the representative of the office of DCGI stated that the status would be informed by them to NPPA after getting information from the concerned field office. Since the status of the validity of the manufacturing license granted to M/s Synokem Pharmaceuticals Limited is uncertain as on date; the Authority deferred the retail price fixation in eleven cases as mentioned in **Table 3.**

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Table No. 3: Deferred cases

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.) as per uploaded draft calculation sheet
(1)	(2)	(3)	(4)	(5)	(6)
4 (ii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayer tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Aristo Pharmaceuticals Pvt. Ltd.	14.27
4 (iii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayer tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Aristo Pharmaceuticals Pvt. Ltd.	15.61
4 (iv)	Telmisartan & Cilnidipine Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Limited	10.39
4 (xxvii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (extended release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Primus Remedies Pvt. Ltd.	16.96
4 (xxviii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Primus Remedies Pvt. Ltd.	17.89

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.) as per uploaded draft calculation sheet
(1)	(2)	(3)	(4)	(5)	(6)
		IP 1000mg (extended release)			
4 (xxxix) a	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Limited	13.35
4 (xxxix) b	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Limited	15.03
4 (xxxix) c	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Limited	13.35
4 (xxxix)	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Limited	15.03
(xlvii) a	Teneligliptin, Dapagliflozin & Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	12.15
(xlvii) b	Teneligliptin, Dapagliflozin & Metformin Hydrochloride	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark	13.39



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.) as per uploaded draft calculation sheet
(1)	(2)	(3)	(4)	(5)	(6)
	(Sustained Release) Tablets	eq. to Teneiglipitin 20mg Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Sustained Release)		Pharmaceuticals Limited	

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted

6. Agenda item no. 6 –Minutes of 57th meeting of Multidisciplinary Committee of Experts held on 27.02.2024.

6.1 Noted

7. Agenda item no. 7 –Minutes of 58th meeting of Multidisciplinary Committee of Experts held on 04.03.2024.

7.1 Noted

8. Agenda item no. 8 –Revision of ceiling price based on Review Orders under NLEM 2022.

8.1 The Authority noted that NPPA is in receipt of following review orders in relation to fixation of ceiling price fixed under NLEM 2022 issued by the Department of Pharmaceuticals (DoP):

Table 4: Review Orders of DoP

S.No.	Date & No. of Review Order	Formulation and Notification
1.	Order no. 31015/21/2023-Pricing dated 08.02.2024	'Cefuroxime Oral Liquid 125mg/5ml' of M/s Glenmark Pharmaceuticals Limited against NPPA notification S.O No. 5939(E) dated 19.12.2022
2.	Order no. 31015/12/2023-Pricing dated 19.02.2024	'Montelukast Tablet 5mg' of M/s RPG Life Sciences Limited against NPPA notification S.O No. 5939(E) dated 19.12.2022
3.	Order no. 31015/13/2023-Pricing dated 22.02.2024	'Mycophenolate Mofetil Tablet 500mg' of M/s RPG Life Sciences Limited against NPPA notification S.O No. 5938(E) dated 19.12.2022

8.2 The Authority noted that based on the review orders, in the above three cases (given in **Table 4** above) draft calculation sheets with revised ceiling prices were uploaded on NPPA website for comments, if any. It was also informed to the Authority that no representations have been received in these cases. The Authority deliberated upon the matter in detail and approved the ceiling prices as mentioned in Column 5 of **Table 5** based on the review orders. It was noted that the prices have been calculated after giving effect of WPI increase of 12.1218% w.e.f 1.04.2023. It was further decided that said ceiling prices may be revised to prices as mentioned in Column no. 6 of Table 5 below, based on WPI increase of (+)0.00551% w.e.f. 01.04.2024.

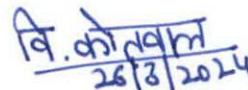
Table 5: Revision in Ceiling Prices based on Review Orders

S. No	Formulation	Dosage form(s) and strength(s)	Current Ceiling Price (in Rs)	Revised Ceiling Price (in Rs) [based on review order]	Revised ceiling prices (in Rs) [w.e.f 01.04.2024]	Unit
1	2	3	4	5	6	7
1.	Cefuroxime	Oral Liquid 125mg/5ml	5.28	5.31	5.31	1 ml
2.	Montelukast	Tablet 5mg	11.72	12.01	12.01	1 tablet
3.	Mycophenolate Mofetil	Tablet 500mg	73.88	74.59	74.59	1 tablet

9. Agenda item no. 9 – Wholesale Price Index as per Para 16 of DPCO 2013 to be applicable from 01.04.2024.

9.1. The Authority noted that DPIIT, Ministry of Commerce and Industry, Government of India has confirmed the monthly final Wholesale Price Indices (WPI) of all commodities for the year 2022 and 2023 vide O.M. OEA-11025(13)/18/2017-WPD-Part(256) dated 19.03.2024. The Authority deliberated upon the matter in detail and as per provisions of DPCO, 2013 approved the WPI @ (+)0.00551% to be applicable on scheduled formulations w.e.f. 01.04.2024. The Authority further decided to issue an Office Memorandum intimating the WPI to be applicable w.e.f. 01.04.2024 and to issue notification (s) for revised ceiling price of scheduled formulations based on WPI @ (+)0.00551% to be effective from 01.04.2024.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.


 (Dr. Vinod Kotwal)
 Member Secretary